DUFNER Instrumente GmbH
Fabrik ärztlicher Instrumente
Medizintechnik
Föhrenstr. 9 · D-78532 Tuttlingen
Fed. Rep. of Germany

FEB - 5 2001

K002877

# 2. 510(k) SUMMARY of Safety and Effectiveness

## Dufner Instrumente GmbH

As required by Section 807.92(c)

**2.1 Submitter:** [807.92 (a)(1)]

Dufner Instrumente GmbH
Föhrenstr. 9
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Germany

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**2.2 Contact Person:** [807.92 (a)(1)]

Dagmar S. Mäser
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The Netherlands

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**2.3 Date Summary Prepared:** [807.92 (a)(1)]

August 14, 2000

**2.4 Device Names:** [807.92 (a)(2)]

**Proprietary** DUFNER MICTEC® Endoscopes & Accessories

**Common** Endoscopic Instruments

| Classification Names | Product Code | CFR Reg'n |
|---|---|---|
| Laparoscope, General & Plastic Surgery | 78 GCJ | 876.1500 |
| Laparoscope, Gynecologic (and Accessories) | 85 HET | 884.1720 |
| Device, Electrosurgical, Cutting & Coagulation & Accessories | 79 GEI | 878.4400 |

**2.5 Reason for Submission:**

New Devices

## 2.6 Predicate Devices: [807.92 (a)(3)]

| | |
|---|---|
| Optus Laparoscopes and Operating Laparoscopes | K 945266 |
| Optus Thoracoscopes | K 945263 |
| Bissinger Detachable Bipolar Coagulation Forceps | K 970968 |
| Bissinger Cables | K 981919 |
| Endoscopic Electrosurgical Instruments | K 972008 |
| Optus Sinuscopes and Accessories | K 944656 |

Laparoscopic Accessories produced by a wide range of manufacturers, including: [1]

Jarit (J. Jamner Surgical Instruments, Inc.)
Snowden-Pencer, Inc.
SurgiTech, Inc. (Surgical Technologies International, Inc.)
United States Surgical Corp.
Allegiance Healthcare Corp.

## 2.7 Device Description: [807.92(a)(4)+(6)]

DUFNER MICTEC® **endoscopes and thoracoscopes** are comprised of a rigid, panoramic telescope which uses rod lens technology. The body contact portions are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

**Laparoscopic and thoracoscopic accessories** are composed of reusable handle and shaft assemblies and removable, reusable tip assemblies. Needle holders and other Class I devices included in the endoscopic catalogs may be one-piece. The instruments are designed and manufactured specifically for the purpose of manipulating soft tissue structures (grasping, cutting, dissecting, coagulating and suturing).

## 2.8 Intended Use: [807.92 (a)(5)]

Endoscopic procedures in general, gynecologic, gastro-enterology/ urology and thoracic surgery in children and adults.

## 2.9 Industry Standards/Performance Data: [807.92 (d)]

DUFNER certifies compliance with relevant ISO/EN/ASTM/ AAMI/ANSI/IEC and other device-related standards that apply to the manufacture, packaging, labeling, and reprocessing of subject devices including the validation of these processes.

## 2.10 Summary of Testing

All materials used in the composition of MICTEC Endoscopes and Thoracoscopes and Accessories were subjected to performance and physical tests to evaluate safety, effectiveness, and reliability of the

[1] The 510(k) numbers for SE accessories by these manufacturers could not be determined.

devices. All results were in conformance with the cited harmonized device standards.

## 2.11 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The DUFNER MICTEC® Endoscopic Instruments & Accessories have the same intended use as the predicate devices. They are made of the same material. Slight modifications in design and technology do not adversely affect the safety and effectiveness of these devices.

In summary, the

- intended use
- performance attributes
- materials and
- basic design

are identical (endoscopes and HF accessories) and identical/ substantially equivalent (other accessories) to SE devices.

**The results of design validation raise no new issues of safety and effectiveness.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2001

Dufner Instrumente GmbH
c/o Ms. Dagmar S. Mäser
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K002877
Trade Name: MICTEC Endoscopes and Accessories
Regulatory Class: II
Product Code: GEI, GCJ, HET
Dated: December 19, 2000
Received: December 21, 2000

Dear Ms. Mäser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number** K002877

**Device Name** **MICTEC® Endoscopic Instruments**

# INDICATIONS FOR USE

DUFNER MICTEC® Endoscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/thoracoscopic closed and minimally invasive procedures in children and adults.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002877

Prescription Use ✓ OR Over-The-Counter Use _____

(Per CFR 801 109)

(Optional Format 1-2-96)